

**Notice of Allowability**

Application No.

10/694,001

Applicant(s)

SCHOLKENS ET AL.

Examiner

Raymond J. Henley III

Art Unit

1614

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the papers filed January 30, 2006 and April 7, 2006.
2. ☒ The allowed claim(s) is/are 16,20-25,30-35 and 71-93.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date 1/30/06 & 4/7/06
- ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
- ☒ Examiner's Amendment/Comment of Examiner
- ☒ Examiner's Statement of Reasons for Allowance
- ☐ Other \_\_\_\_\_

Single  
document

**RAYMOND HENLEY III**  
**PRIMARY EXAMINER**

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**EXAMINER'S COMMENTS AND REASONS FOR ALLOWANCE*****Comments***

A request for continued examination, ("RCE"), under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance. Because this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicants' submissions filed on January 30, 2006, (RCE and Information Disclosure Statement) and on April 7, 2006 have been entered.

As reflected by the attached, completed copies of form PTO/SB/08, (8 sheets), the Examiner has considered the cited references.

***Reasons for Allowance***

Present claim 16 is representative of the presently claimed subject matter and reads:

16. (Currently Amended) A method for reducing the risk of a cardiovascular event in a patient with an increased cardiovascular risk and no evidence of left ventricular dysfunction, which comprises administering to the patient an effective amount of ramipril or ~~[[.]]~~ ramiprilat, or a pharmaceutically acceptable salt of ramipril or ramiprilat derivative thereof, wherein the cardiovascular event is stroke, cardiovascular death or myocardial infarction.

The closest art remains Olukotun et al., (U.S. Patent No. 5,622,985) as relied on by the Examiner in the Office action dated July 29, 2004 as the basis for rejecting the claims under 35 U.S.C. § 103(c). The conclusion of obviousness set forth in that Office action was effectively overcome by Applicants' remarks set forth in their amendment filed January 27, 2005 at pages 8-

Art Unit: 1614

12. In particular, Applicants persuasively supported their position that the reduction of the risk of cardiovascular events in patients with an increased risk thereof and in whom there was no evidence of left ventricular dysfunction would not have been obvious to one of ordinary skill in the art. The reason for this position was because in patients of the type claimed, i.e., at risk of stroke, cardiovascular death or myocardial infarction, the angiotensin converting enzyme, ("ACE"), inhibitor, ramipril, was believed to be effective essentially due to the effect of this compound of increasing left ventricular function. This is in contrast to the requirement of the present claims wherein the patient has no evidence of left ventricular dysfunction.

The art newly cited by Applicants is nor more than cumulative to the subject matter of the references already of record and fully considered by the Examiner.

Accordingly, claims 16, 20-25, 30-35 and 71-93, all of the claims in the application, remain in condition for allowance.


Any comments regarding the above remarks by the Examiner considered necessary by Applicants must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1614

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Raymond J Henley III  
Primary Examiner  
Art Unit 1614

April 19, 2006